

**NON-CONFORMANCE MONITORING AND CONTROL
TECHNIQUES FOR AN IMPLANTABLE MEDICAL DEVICE**

Abstract of the Invention

Disclosed is a method and apparatus for determining whether an implantable drug delivery device is conforming to the performance requirements of the device or the needs of the patient. The system includes an implantable drug delivery device having stored therein at least one drug, a nonconformance monitor module monitoring pump parameters, an external programmer in telemetric communication with the implantable drug delivery device and having a nonconformance management module for determining whether the the device is conforming to performance requirements, and to determine what action should be taken if non-conformance is determined. If the nonconformance management module identifies nonconformance, it determines what action should be taken for the particular non-conformance. The nonconformance management module will either invoke a pump programming change, or schedule and appointment or notify the patient that a non-programming change should be made.